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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,611	03/29/2004	Atsushi Suzuki	251067US0CONT	9751

22850 7590 06/01/2005

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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/810,611	Applicant(s) SUZUKI ET AL.	
	Examiner Dwayne C. Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14MAR2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,7,8 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,7,8 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

S.O.O.

DETAILED ACTION

Status of Claims

1. Claims 4, 5, 7, 8, 11-19 are pending.
2. Claims 4, 5, 7, 8, 11-19 are rejected.

Response to Arguments

3. Applicant's arguments filed March 14, 2005 have been fully considered but they are not persuasive. Applicant argues that Cheng et al. does not render the instantly claimed subject matter obvious because the phrase "ester bond residue" has been removed from independent claim 4. However, it is well within the purview of the skilled artisan to derivatize the carboxylic acid moiety with amino compounds to easily generate amide bond residues, (see Solomons of Organic Chemistry, 3rd Edition, pages 786-819). The skilled artisan has the common skills and knowledge to readily convert from a carboxylic acid moiety, such as the compound of formula (I), into other carboxylic acid derivatives, namely carboxylic anhydrides, carboxylic acid esters, carboxylic acid amides, and even acyl halides. For these reasons, and those of record, the instantly claimed subject matter is found obvious in view of Cheng et al. al. as well as the common knowledge of one having ordinary skill in the art of organic chemistry, as evidenced by Solomons.

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Priority

4. Receipt is acknowledged of papers, including English translation of JP2001-169261, submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

5. The rejection of claims 4-6, 9, and 10 under 35 U.S.C. 102(b) as being clearly anticipated by Cheng, J. T. et al. of abstract of XP-002219274 is withdrawn in response to amendment of March 14, 2005.

6. The rejection of claim 4 under 35 U.S.C. 102(b) as being clearly anticipated by Okawa et al. of EP 1,172,112 A2 is withdrawn in response to the remarks and submission of the translation file on March 14, 2005.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains: Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4, 5, 7, 8, 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng, J. T. et al. of abstract of XP-002219274. Cheng, J. T. et al. teach of treating hypertension with the administration of chlorogenic acid and other caffeoylquinic acids, namely methyl chlorogenate, which are embraced by the compounds of formula (I), (see abstract). Cheng, J. T. et al. are silent to pharmaceutical dosages and modes of administration and amide-containing derivatives of chlorogenic acid. However, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds of Cheng, J. T. et al.

Obviousness-type Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. The provisional rejection of claims 4, 5, 7, 8, 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 and 11-31 of copending Application No. 09/944,079 is maintained and repeated.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the copending Application No. 09/944,079 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and the copending Application No. 09/944,079 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising'

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incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

13. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. The provisional rejection of claims 4, 5, 7, 8, 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-19 and 23-26 of copending Application No. 10/192,075 is maintained and repeated.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the copending Application No. 10/192,075 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and the copending Application No. 10/192,075 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

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15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. The provisional rejection of claims 4, 5, 7, 8, 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 10/626,708 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the copending Application No. 10/626,708 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and the copending Application No. 10/626,708 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. The rejection of claims 4, 5, 7, 8, 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-17 of U.S. Patent No. 6,458,392 is maintained and repeated. Although the conflicting claims are

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not identical, they are not patentably distinct from each other because both the instant invention and U.S. Patent No. 6,458,392 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and U.S. Patent No. 6,458,392 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.


Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov) from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR

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Business Center (EBC) at 1-866-217-9197 (toll free).


DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614

May 27, 2005